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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,213	11/14/2001	Brenda F. Baker	RTS-0327	1275

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EXAMINER	
SCHMIDT, MARY M	

ART UNIT	PAPER NUMBER
1635	4

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/000,213	Applicant(s) BAKER ET AL.	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to compounds targeted to vitamin D nuclear receptor (VDR) and methods of using said compounds, classifiable in class 435, subclasses 6, 91.1, 325, 366 and 375; class 536, subclass 23.1, 24.31, 24.33, 24.5 and class 514, subclass 44.

II. Claims 1, 19 and 20, drawn to compounds targeted to VDR-type I, classifiable in class 435, subclasses 6, 91.1, 325, 366 and 375; class 536, subclass 23.1, 24.31, 24.33, 24.5 and class 514, subclass 44.

III. Claims 1, 19 and 20, drawn to compounds targeted to VDR-type-II, classifiable in class 435, subclasses 6, 91.1, 325, 366 and 375; class 536, subclass 23.1, 24.31, 24.33, 24.5 and class 514, subclass 44.

IV. Claims 1, 19 and 20, drawn to compounds targeted to VDR-type III, classifiable in class 435, subclasses 6, 91.1, 325, 366 and 375; class 536, subclass 23.1, 24.31, 24.33, 24.5 and class 514, subclass 44.

V. Claims 1, 19 and 20, drawn to compounds targeted to VDR-type IV, classifiable in class 435, subclasses 6, 91.1, 325, 366 and 375; class 536, subclass 23.1, 24.31, 24.33, 24.5 and class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I, II, III, IV and V are unrelated from each of the other Inventions since they are each drawn to nucleic acid compositions which target different target gene sequences: VDR, VDR-type I, VDR-type II, VDR-type III and VDR-type IV, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects since the compositions of each invention are structurally different (claim 19 requires that the compounds hybridize selectively to the individual variant receptor sequence, and thus they must be structurally distinct, each having a nucleic acid sequence which binds only to one of the VDR or VDR receptor variant sequences) and as such they target and inhibit a different target gene sequence. Each of the target gene sequences is patentably distinct as per MPEP 803.04 which states: "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq." Therefore, compounds which target different target gene sequences constitute patentably distinct sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and the search

required for each of Group I, II, III, IV or V is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Furthermore, upon election of Group I above, the following restriction is required for the individual sequences of claim 3.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in claim 3 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434).

Claim 3 specifically claims antisense SEQ ID NOS 14, 16, 18, 19, 21, 24, 25, 27, 28, 30, 31, 32, 33, 34, 35, 38, 39, 40, 41, 42, 44, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 59, 60, 62, 63, 66, 67, 68, 72, 76, 78, 79, 80, 81, 82, 85, 88, 90 or 91, which are targeted to and modulates the expression of the gene vitamin D nuclear receptor (VDR). Although the antisense sequences claimed each target and modulate expression of the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of the

VDR gene, and each antisense, upon binding to the VDR gene, functionally modulates (increases or decreases) the expression of the gene and to varying degree (per applicants' Table 1 in the specification). Furthermore, a search of more than one (1) of the antisense sequences claimed in claim 3 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense sequence from claim 3.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
July 16, 2002